Prescription Drug User Fee Act (PDUFA)
FDA and Stakeholders Public Meeting

Comments of
National Consumers League

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Good morning. I am very pleased to able to comment on the Prescription Drug User Fee Act (PDUFA) today on behalf of the National Consumers League. I serve as the Health Policy Associate for the League. NCL is America's oldest nonprofit consumer advocacy organization, and has been working to protect the public's health and safety for over 100 hundred years. From the first Pure Food and Drug laws passed in 1906 and the Food, Drug, and Cosmetic Act of 1938, to the recent FDA Modernization Act, NCL has been instrumental in ensuring that the public's well being is adequately protected and represented.

NCL is concerned that PDUFA is not adequately protecting the public's interests, and instead serves the regulated industry. We are concerned about the conflict of interest inherent in industry funding of government operations, particularly when the industry is allowed to set the goals, direct the funds, and make demands about how the Agency conducts its regulatory functions. We are also concerned that while industry has input into these decisions, the public does not. When PDUFA was created, FDA consulted with Congress and the industry, leaving consumers, who are FDA's real customers, out of the loop. Since drug approval decisions have a direct impact on consumers, who are the end users, public input is an absolute necessity.

NCL fully supports the ideal that enhanced drug approval processes benefit everyone, however, faster approval does not always mean better. With review goals shortening and becoming more stringent, there is increased pressure for FDA to meet them by hurrying the drug approval process, possibly to the detriment of the public. Safety, effectiveness, and necessity should be the stated goals of drug approval and review, not speed. Another concern about the current review goals is that they do not sufficiently discriminate between true priority drugs—treatments for severe or life-threatening illness and pain, rare disorders, conditions where no current treatments exist, or for new drugs that confer significant safety and efficacy benefits over current drugs—and the "me too" drugs which are the 5th, 8th, or 10th drug in their class, offering little if any added benefits in safety or efficacy.

Under PDUFA II, FDA is becoming too close to industry, with procedural goals established to increase FDA's responsiveness to, and communications with, industry sponsors. While it is necessary for FDA and industry to have open channels of communication and dialogue to ensure that the proper information and data are submitted and evaluated, these goals give the appearance that FDA serves industry as its primary customer, not the American public. FDA should serve the public first and foremost, and be responsible for protecting the public's health and well being, not the industry's.

PDUFA has had a dramatic effect on the drug review process, with FDA resources more than doubling since its enactment in 1992 and review staff increasing almost 60 percent from 1993 to 1997. But at what expense does this revenue stream come? According to an FDA Background Information Paper available on FDA's website, "assuring that enough appropriated funds are spent on the process for the review of human drug applications to meet requirements of PDUFA, and at the same time spending our resources in a way that best protects the health and safety of the American people is

becoming increasingly difficult...Since 1992 FDA has not received increased appropriations to cover the costs of the across-the-board pay increases that must be given to all employees. The result is that our workforce and real resources for most programs other than PDUFA have contracted each year since 1992 while we struggle to assure that enough funds are spent on the drug review process to meet this PDUFA requirement." Thus, PDUFA costs the agency more than it gives, robbing badly needed resources from other important program areas that are vital to protecting the public's health. As a result, the agency is in jeopardy of losing the support and confidence of the American people, something it cannot afford to do.

One prime example of how FDA priorities are affecting public health is the food safety and inspection programs at FDA. Food processing plants are inspected an average of once every ten years—there are 700 inspectors for nearly 55,000 plants—and only two percent of all imported foods are inspected. As a result, foodborne illnesses and outbreaks are on the rise, the majority of which involve FDA-inspected products. As a comparison, USDA-inspected meat and poultry plants have at least one inspector assigned to every plant under USDA purview, and all meat and poultry is under continuous, daily inspection. Because Congress and the industry continue to focus on the drug approval side of the FDA, the food protection operations continue to decline and put American consumers at risk. Once again, Congress must fund the FDA fully for all its activities and should not rely on industry to supplement or even supplant government resources.

Further, adverse events reporting and post market surveillance, along with the review and monitoring of direct-to-consumer advertisements and off-label promotion of prescription drugs are also suffering because of a lack of sufficient resources. This comes at a time when prescription drug use in on the rise and is expected to grow dramatically in upcoming years. With more and more drugs being approved, and increasing numbers of Americans using them, many on multiple drug therapies, and the growing trend toward self medication with dietary supplements and over-the-counter drugs, the risk for adverse events and dangerous interactions will increase, making drug monitoring and reporting functions by FDA more vital than ever. Without proper funding, however, FDA will not be able to keep pace.

FDA should not have to rely on industry to fund its operations. Congress must adequately fund FDA in all program areas. If all the focus and attention are placed on drug approval, partly financed by industry user fees, what will happen to the other programs FDA oversees? What will become of food safety and inspections, an area where real problems are already evident? And what will become of the public's health and safety? While the budgets for PDUFA-funded operations continue to grow, many programs of equal importance and weight, particularly to the public's health and well being, continue to languish. Congress cannot let the industry finance the FDA and dictate how the money is to be spent. There is too much at stake and too many lives at risk.

Finally, if FDA budgets continue to diminish at the expense of PDUFA-related programs and review goals, FDA's ability to protect the public's health will diminish, along with the public's trust in FDA as well. Thank you.